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ROBERT M. KASS
12716 42nd Avenue
Chippewa Falls, WI 54729-6602
— [REDACTED] —
(715) 720-7739

July 28, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fische5rs Lane, Room 1061
Rockville, Maryland 20857-0003

RE: Docket No. 98N-1265

Dear FDA,

I am sending this leetter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain health care products from the provider of their choice. It also infringes on the rights of compounding pharomicists to serve the public's medical needs based on the patient's and physician's choice of method of receiving certain perscribed medications and other health balancing and health maintenance items.

As a heath care consumer, I feel strongly that there should be no restrictions to the deliver of a compounded medication perscribed for me, regardless of where I mal live or may travel.

My wife had been on Fosimax for 4 or 5 years to help her with premature onset of osteoperosis with no improvement in her bone marrow density. She began using a compounded medication containing progesterone and discontinued the use of Fosimax. In nine months of use she had a 5% overall increase in her bone marrow density. The use of the compounded progesterone cream also provided her with relief of otherwise uncontrollable hormone imbalances which she had suffered the miserable effects of for over three years.

We are fortunate in Wisconsin to have several compounding pharmacies in our State but should we relocate out of state, the MOU as it is currently written would restrict our ability to obtain compounds that are vital to my wife's health and well being.

Thank you.

Sincerely,



Robert M. Kass

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98N-1265 State of residence - Wisconsin

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12716 42nd Avenue
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